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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,516	11/21/2003	Yiwen Tang	50623.304	3018

7590 03/20/2007
Victor Repkin
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,516	TANG ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/18/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,5-8, 17 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically the written description in the specification only gives support for a limited number of polymers that would have a glass transition temperature less than about -50°C for the first polymer and greater than about -50°C for the second polymer. There is not enough written description to claim all polymers with a glass transition temperature of greater than or less than -50°C . It is suggested by the examiner that in order to overcome this rejection applicants amend their claims to include specific examples supported within the specification for the first polymer such as PCL and the polymeric additive such as 3-PHB.

Claims 1,5-8, 17 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specific polymers detailed within the specification with a glass transition temperature of below about -50°C for the first polymer such as PCL and greater than about -50°C for the polymeric additive such as

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3-PHB, does not reasonably provide enablement for all polymers with a glass transition temperature greater than or less than -50°C . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The limitations in the above claims are reached through claims because the limitations would read on polymers yet to be synthesized or analyzed in the art with the recited transition glass temperatures. It is suggested by the examiner that in order to overcome this rejection applicants amend their claims to include specific examples supported within the specification for the first polymer such as PCL and the polymeric additive such as 3-PHB.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically each claim recites that the polymeric additive can be selected from a group including 3-PHB, this is considered confusing and indefinite because in example 3 within the specification the only polymer used for coating the stent was 3-PHB, therefore from the example it would appear to one of ordinary skill in the art that 3-PHB is in fact the first biologically erodible polymer and not an additive.

Claims 12-14 and 29-31 recites the limitation "wherein the mass of the first polymer and the polymeric additive is" in line 1. There is insufficient antecedent basis for

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this limitation in the claim, because a polymeric additive is not claimed in either claim 1 or 17. Furthermore claim 29 recites the limitation "medical article" when claim 17 is drawn to a method.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-11, 15-28 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by DeSimone et al. (US 2004/0181271 A1).

DeSimone teaches a intraluminal prosthesis (including stents) comprised of an erodible polymeric material and a coating which can be comprised of PCL, PHB, poly(PHB-co-PHV), PHV, PGA, PLA ect. and blends thereof. See [0028],[0035]-[0037],[0043] and claims 1,36,38 and 39. Pharmacological agents could be incorporated within the stent or within the coating, since the coating can cover a stent containing the active this would meet the limitation in claim 16 in which a topcoat layer is disposed over a drug reservoir layer. Regarding the limitations on the glass transition temperatures of the first polymer and the polymeric additive, DeSimone teaches that exemplary polymeric materials have a glass transition temperature between about 60°C to about -60°C. Regarding claims 6-8 and 23-25, DeSimone teaches that the MW of the polymers may be from 1,000 to 4,000,000 Daltons, from applicants own specification

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PHB with a MW between about 100,000 to about 500,000 Daltons would have a T_g of about 10°C , thus since DeSimone teaches PHB within applicants disclosed MW range the limitations of the disclosed T_g are met. See [0033] of applicants US publication 2005/0112171 A1.

Claims 1-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (EP 0 970,711 A2, disclosed in applicants IDS).

Hossainy teaches a process for providing coated stents, the stent coating can be comprised of PCL, PHB, PHV, PGA ect. and blends thereof. See abstract, [0022], [0025], [0029]-[0031]. The coating could be a top coating applied to delay the release of a pharmaceutical agent or the coating can be used as a matrix for the delivery of a pharmaceutically active material. Regarding claims 12-14 and 29-31 Hossainy teaches that PCL and glycolide could be used in a blend of from about 35:65 to 90:10, within applicants claimed mass ratio. Regarding the limitation of the first polymer and the polymeric additive based upon their glass transition temperatures, it appears as though applicants are claiming the properties of an old combination for a stent coating, since the polymeric blend recited within Hossainy is the same as applicants claimed invention the limitation is met because the same polymers will inherently have the same properties. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re

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Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Also as evidenced by the recited teachings of Polymeric Materials Encyclopedia, the glass transition temperature of PCL is -60°C over a wide MW range, therefore it appears as though the glass transition temperature is not dependent on the MW of the polymer, at least for larger polymers. Polymeric Materials Encyclopedia, Salamone, J.C., 1996, CRC Press, Inc., page 5687).

Claims 1-4, 11, 16-21, 28 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Hossainy et al. (US 2001/0014717 A1, '717 from hereon, disclosed in applicants IDS).

'717 teaches a coating for implantable devices (including stents), the coating can be comprised of PCL, PHB, poly(PHB-co-PHV), PHV, PGA, PLA ect., the T_g of PCL was -60°C . See abstract, [0014],[0034],[0041],[0050]-[0051] and table 3. The polymeric materials were described as being capable of containing an active agent.

Claim Rejections - 35 USC § 103

Claims rejected under 35 U.S.C. 103(a) as being unpatentable over DeSimone et al. (US 2004/0181271 A1).

DeSimone is disclosed above. DeSimone does not disclose a specific ratio of the polymeric blends used in the coating material. It would have been obvious however to the skilled artisan through routine experimentation and optimization to vary the mass ratios of the polymeric blend to achieve the desired characteristics for the coating. Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such

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concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (EP 0 970,711 A2, disclosed in applicants IDS) in view of DeSimone et al. (US 2004/0181271 A1) and/or in view of Hossainy et al. (US 2001/0014717 A1, '717 from hereon, disclosed in applicants IDS).

Hossainy is disclosed above.

Hossainy does not specifically mention the glass transition temperatures of the polymers used in the polymeric blend.

DeSimone and '717 are disclosed above. These references are used mainly to show that the polymeric materials described within Hossainy were already known to have the same T_g values claimed by applicants.

It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to modify the polymers disclosed in Hossainy and add the same type of polymers but with the specific T_g values disclosed within DeSimone and/or '717. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a

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composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of polymers useful as coatings for an intraluminal prosthesis. One of ordinary skill in the art would have a reasonable expectation of success in combining the references above to produce a coated stent because all of the references are related to the same general field of endeavor and the references all use the same types of polymers in the coatings. The advantage of using polymers with specific T_g values as disclosed within DeSimone would be that the polymeric material could be annealed during the manufacturing process to modify the crystallinity so that the physical properties of the polymeric material can be accurately controlled. Annealing includes heating the polymeric material to a temperature between the T_g and the T_m of the polymer, therefore it is useful to accurately find these properties in the literature before the manufacturing process. It therefore follows that the instant claims define prime facie obvious subject matter.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'm. hartley', with a large, stylized flourish at the end.

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER